

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

S. ROSE et al.

Confirmation No.: **3864**

Application No.: **10/557,072**

Group Art Unit: **1621**

Filing Date: **April 18, 2006**

Examiner: **O'SULLIVAN, Peter G.**

US Patent No.: **7,541,493**

Issue Date: **June 2, 2009**

For: **Modafinil Synthesis Process**

ELECTRONICALLY FILED
DATE OF DEPOSIT: July 31, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 422 to 577 days, is respectfully requested.

REMARKS

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F. Supp. 2d 138;

88 USPQ 2d 1538), the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” “B delay” begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the “overlap” issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B). It is Patentee’s understanding that for purposes of calculating “B Delay,” the Office measured application pendency as beginning on 371 COMPLETION DATE, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, 37 C.F.R. § 1.702(b) states that when calculating “B Delay” for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that the national stage commences under 35 U.S.C. § 371(b) or (f):

(b) Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application “commences.”

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b).

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. According to MPEP § 1893.01, the national stage is commenced under 35 U.S.C. § 371(f) when the applicant makes an express request and complies with the applicable requirements of 35 U.S.C. § 371(c):

Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01.

35 U.S.C. § 371(d) sets forth the applicable requirements under 35 U.S.C. § 371(c) needed for commencement. Specifically, 35 U.S.C. § 371(d) permits the national stage to commence under 35 U.S.C. § 371(f) even if the requirements of subsection (c)(1), the translation requirement of (c)(2), and/or the requirements of (c)(4) are complied with after the date of commencement, if such delay is permitted by the Director.

(d) The requirement with respect to the national fee referred to in subsection (c)(1), the translation referred to in subsection (c)(2), and the oath or declaration referred to in subsection (c)(4) of this section shall be complied with by the date of the commencement of the national stage or by such later time as may be fixed by the Director. ... The payment of a surcharge may be required as a condition of accepting the national fee referred to in subsection (c)(1) or the oath or declaration referred to in subsection (c)(4) of this section if these requirements are not met by the date of the commencement of the national stage. ... 35 U.S.C. § 371(d).

Pursuant to 37 C.F.R. § 1.495 and MPEP 1893.01(a)(1), the Director has fixed a later time after commencement for fulfilling the requirements of, *inter alia*, 35 U.S.C. § 371(c)(4). According to MPEP 1893.01(a)(1), the requirements of 35 U.S.C. § 371(c)(4) can be fulfilled 2

months from the date the Office notifies the Applicant of the need to satisfy (c)(4) or 32 months from the priority date, whichever is later. This period may be extended for up to 5 additional months.

If the basic national fee has been paid and the copy of the international application (if required) has been received by expiration of 30 months from the priority date, but the required oath or declaration, translation, search fee (37 CFR 1.492(b)), examination fee (37 CFR 1.492(c)), or application size fee (37 CFR 1.492(j)) has not been filed prior to commencement of the national stage (see MPEP § 1893.01), the Office will send applicant a notice identifying any deficiency and provide a period of time to correct the deficiency as set forth in 37 CFR 1.495(c). The time period usually set is 2 months from the date of the notification by the Office or 32 months from the priority date, whichever is later. This period may be extended for up to 5 additional months pursuant to the provisions of 37 CFR 1.136(a). Failure to timely file the proper reply to the notification will result in abandonment of the national stage application. The processing fee set forth in 37 CFR 1.492(i) will be required for acceptance of an English translation of the international application later than the expiration of thirty months after the priority date, and the surcharge fee set forth in 37 CFR 1.492(h) will be required for acceptance of any of the search fee, examination fee, or oath or declaration of the inventor after the date of commencement. 37 CFR 1.495(c)(3). MPEP 1893.01(a)(1)

In view of the foregoing, the “actual filing date” of a U.S. national stage application filed under 35 U.S.C. § 371(f), for purposes of calculating “B Delay” under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that the basic national fee has been paid and the copy of the international application (if required) has been received.¹

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

“A Delay”

U.S. Patent Application Serial No. 10/557,072 (“the ‘072 application”), which issued as U.S. Patent No. 7,541,493 (“the ‘493 patent”) on June 2, 2009, was the National Stage of

¹ In contrast to reliance on “the expiration of 30 months from the priority date” for measuring “B Delay,” the beginning of the relevant period for purposes of calculating “A Delay” is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 37 C.F.R. § 1.702(a)(1).

PCT/IB2004/001409, filed on May 5, 2004, and had a § 371 (c)(1), (2), (4) date of April 18, 2006.

Under 35 U.S.C. § 154(b)(1)(A), Patentee is entitled to an adjustment of the term of the '493 patent of 422 days, the number of days attributable to PTO examination delay ("A Delay"). The A Delay consists of the following: (1) A period of 378 days pursuant to 35 U.S.C. § 154(b)(1)(A)(i) due to the PTO's failure to mail an action under 35 U.S.C. § 132 not later than 14 months from the date on which an international application fulfilled the requirements of section 35 U.S.C. § 371; this period consists of the length of time from June 18, 2007 (14 months after the 371(c)(1), (2), (4) date of the '072 application) to June 30, 2008 (the mailing date of the First Office Action); and (2) A period of 44 days pursuant to 35 U.S.C. § 154(b)(1)(A)(ii) due to the PTO's failure to respond to a reply within 4 months after the date on which a reply was filed; this period consists of the length of time from August 15, 2008 (the date a reply was filed) to January 28, 2009 (the mailing date of the Notice of Allowance).

"B Delay"

The '072 application had a § 371 (f) date of November 15, 2005, which is the date that the request 35 U.S.C. § 371 (f) for national stage commencement was made and the basic national fee was paid. The copy of the international application was received from the International Bureau prior to November 15, 2005. The signed oath or declaration was filed on April 18, 2006 together with the \$130.00 surcharge required for filing the oath or declaration after commencement of the national stage (37 C.F.R. § 1.492(h)).

Under 35 U.S.C. § 154(b)(1)(B), Patentee is entitled to an additional adjustment of the term of the '493 patent of 199 days due to the PTO's failure to issue a patent within 3 years after the actual filing date of the application ("B Delay"). The B Delay consists of the length of time from November 15, 2008 (3 years after the national stage commenced under 35 U.S.C. § 371 (f)) to June 2, 2009 (the issue date of the '493 patent).

Overlap of "A Delay" and "B Delay"

Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment

granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” For the ‘493 patent, 44 days of the A Delay overlaps with the B Delay period; this period consists of the length of time from December 15, 2008 to January 28, 2009. Therefore, the 44 day period of overlap is excluded for the patent term adjustment.

Total Period of PTO Delay

The total period of PTO delay is 577 days, which is the sum of the period of A Delay (422 days) and the period of B Delay (199 days) minus the period of overlap (44 days).

Applicant Delay

Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 0 days as determined by the Office.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

The correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 577 days, which is the difference between the total period of PTO delay (577 days) and the period of applicant delay (0 days).

DOCKET NO.: CP242
Application No.: 10/557,072
US Patent No.: 7,541,493

PATENT

The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 03-1195.

Respectfully submitted,

/Todd Spradau/

Date: July 31, 2009

Todd W. Spradau
Reg. No. 52,242

CEPHALON, Inc.
41 Moores Road
PO Box 4011
Frazer, PA 19355
Telephone: 610-883-5679
Telefax: 610-727-7651